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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,250	06/24/2003	Robert J. Garabedian	24728-7003 (2024728-70148	4498

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Bingham McCutchen LLP
Suite 1800
Three Embarcadero Center
San Francisco, CA 94111-4067

EXAMINER	
STRAIGHTIFF, MICHAEL PAUL	
ART UNIT	**PAPER NUMBER**
3739	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,250	GARABEDIAN ET AL.	
	Examiner	Art Unit	
	Michael P. Straightiff	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *1-22 and 50-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/23/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/12/2004*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *10/26/2004* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: Page 13, Line 19 reads "disclosed in co-pending U.S. Application Serial No. 10/xxx,xxx". Because the Application Serial No. is not inserted, no application is considered incorporated by reference by the Examiner.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 41-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. In regard to Claim 41, claim recites the limitation "the one or more bosses" in Line 1. There is insufficient antecedent basis for this limitation in the claim. The remaining claims are necessarily rejected as being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 35-39 and 44-49 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,530,922 to Cosman et al.

a. In regard to Claim 35, Cosman et al. disclose "[A] method for performing a compound ablation in the body of a patient, comprising: affixing an alignment device relative to a targeted tissue" (See Cosman et al., Column 7, Lines 19-22; See also Figures 1 and 10), "guiding a plurality of ablation probes within a respective plurality of apertures in the alignment device to place the ablation probes adjacent the targeted tissue in a plurality of regions" (See Cosman et al., Figure 10), and "operating the ablation probes to create a plurality of lesions in the plurality of regions" (See Cosman et al., Column 15, Lines 26-28).

b. In regard to Claim 36, Cosman et al. further disclose "wherein the plurality of ablation probes are operated by transmitting RF energy between at least two of the ablation probes" (See Cosman et al., Column 6, Lines 7-10).

c. In regard to Claim 37, Cosman et al. further disclose "wherein the entire target tissue is ablated" (See Cosman et al., Column 4, Lines 50-54).

d. In regard to Claim 38, Cosman et al. further disclose "wherein the ablation probes are guided within the plurality of apertures in parallel directions" (See Cosman et al., Figure 1, Reference 14; See also Figures 9a – 9c; See also Column 15, Lines 5-7).

e. In regard to Claim 39, Cosman et al. further disclose "wherein the ablation probes are guided within the plurality of apertures in non-parallel directions" (See Cosman et al., Figure 1, Reference 14; See also Figures 9a – 9c; See also Column 15, Lines 5-7).

f. In regard to Claim 44, Cosman et al. further disclose "wherein the ablation probes are operated by generating RF energy to create the plurality of lesions" (See Cosman et al., Column 6, Lines 7-10).

g. In regard to Claim 45, Cosman et al. further disclose "wherein the ablation probes are in contact with the plurality of regions in the target tissue" (See Cosman et al., Figures 1 and 10).

h. In regard to Claim 46, Cosman et al. further disclose "wherein the ablation probes are embedded with the plurality of regions of the target tissue" (See Cosman et al., Figures 1 and 10).

i. In regard to Claim 47, Cosman et al. further disclose "wherein the target tissue is inside the body of the patient" (See Cosman et al., Column 3, Lines 50-54).

j. In regard to Claim 48, Cosman et al. further disclose "wherein the ablation probes are percutaneously guided within the plurality of apertures into the body of the patient" (See Cosman et al., Column 9, Line 67 – Column 10, Line 4).

k. In regard to Claim 49, Cosman et al. further disclose "wherein the target tissue is a tumor" (See Cosman et al., Column 4, Lines 50-54).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. US 2002/0052610 to Skakoon et al. in view of U.S. Patent No. 6,530,922 to Cosman et al.

a. In regard to Claim 23, Cosman et al. disclose "[A] method for performing a compound ablation in the body of a patient, comprising: affixing an alignment device relative to targeted tissue" (See Cosman et al., Column 7, Lines 19-22; See also Figures 1 and 10). Cosman et al. do not meet the limitations "guiding an ablation probe within a first aperture in the alignment device to place the ablation probe adjacent the targeted tissue in a first region" and "guiding the ablation probe within a second different aperture in the alignment device to place the ablation probe adjacent the targeted tissue in a second region". Skakoon et

al. teach "guiding an ablation probe within a first aperture in the alignment device to place the ablation probe adjacent the targeted tissue in a first region" and "guiding the ablation probe within a second different aperture in the alignment device to place the ablation probe adjacent the targeted tissue in a second region and operating the ablation probe again to create a second lesion in the second region" (See Skakoon et al., Paragraph [0065], Lines 10-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to guide the ablation probe within a second different aperture in the alignment device as taught by Skakoon et al. as a step in the method disclosed by Cosman et al. in order to target a second tissue region for ablation.

b. In regard to Claim 24, Skakoon et al. further disclose "completely removing the ablation probe from the first aperture prior to guiding the first ablation probe within the second aperture" (See Skakoon et al., Paragraph [0065], Lines 10-16).

c. In regard to Claim 25, Cosman et al. further disclose "wherein the alternate guiding and operating of the ablation probe is performed for a plurality of regions until the entire target tissue is ablated" (See Cosman et al., Column 4, Lines 50-54).

d. In regard to Claims 26 and 27, Cosman et al. further disclose guiding an ablation probe within the first and second apertures in parallel and non-parallel directions (See Cosman et al., Figure 1, Reference 14; See also Figures 9a – 9c; See also Column 15, Lines 5-7).

e. In regard to Claim 28, Cosman et al./Skakoon et al. disclose "[A] method for performing a compound ablation in the body of a patient" (See Claim 23 Rejection). Cosman et al. do not explicitly meet the limitation "wherein the alignment device comprises a boss or a recess associated within the first aperture, the method further comprising modifying a distance that the ablation probe is guided within the first aperture by abutting a portion of the ablation probe against the boss or recess." Skakoon et al. teach "wherein the alignment device comprises a boss or a recess associated within the first aperture, the method further comprising modifying a distance that the ablation probe is guided within the first aperture by abutting a portion of the ablation probe against the boss or recess" (See Skakoon et al., Figure 30, particular reference to recesses within apertures). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a recess as taught by Skakoon et al. on the alignment device disclosed by Cosman et al. in order to modify the distance that the ablation probe is guided within the aperture.

f. In regard to Claim 29, see Claim 44 Rejection above.

g. In regard to Claim 30, see Claim 45 Rejection above.

h. In regard to Claim 31, see Claim 46 Rejection above.

i. In regard to Claim 32, see Claim 47 Rejection above.

j. In regard to Claim 33, see Claim 48 Rejection above.

k. In regard to Claim 34, see Claim 49 Rejection above.

8. Claims 40 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,530,922 to Cosman et al. in view of U.S. Patent Application Publication No. US 2002/0052610 to Skakoon et al.

a. In regard to Claim 40, see Claim 28 Rejection above.

b. In regard to Claim 43, Cosman et al. discloses "[A] method for performing a compound ablation in the body of a patient" (See Claims 35 and 40 Rejections). Cosman et al. do not explicitly meet the limitation "wherein one or more apertures is associated with one or more inserts, wherein the one or more inserts are removably mounted." Skakoon et al. teach the use of one or more inserts associated with the one or more apertures, wherein the one or more inserts are removably mounted (See Skakoon et al., Figure 30, Reference 3020). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide removably mounted inserts in the one or more apertures as taught by Skakoon et al. in the method disclosed by Cosman et al. in order to control the depth which the ablation probe is able to be deployed into the targeted tissue.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. U.S. Patent No. 5,904,691 to Barnett et al. – Barnett et al. disclose a surgical alignment guide with cylindrical mounting boss disposed on the surface.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Straightiff whose telephone number is (571) 272-4774. The examiner can normally be reached on Monday through Friday 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700